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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,795	CIVELLI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 1 to 10 are pending in the instant application.

2) The preliminary amendment which was filed by Applicant on 29 January of 2002 has not been entered because it does not comply with 37 C.F.R. § 1.121. See M.P.E.P. 714.

3) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figures 4A-1, 4A-2, 13B-1 and 13B-2 of the instant application clearly do not comply with 37 C.F.R. § 1.84(U)(1). Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

4) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Correction is required. See M.P.E.P. 2422.03.

5) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. M.P.E.P. 2422.02 expressly states that "when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the

Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings".

6) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the **nucleotide sequence presented on page 13** of the instant specification. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

7) The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be

incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

8) The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

(b) Cross-Reference to Related Applications.

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(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

There are no provisions for "Footnotes"or "Acknowledgments" in a published patent. Therefore, the information presented on pages 72 and 81 of the instant application should be incorporated into the body of the text of the instant specification.

9) The instant specification is objected to because it contains an abstract within the body of the specification, specifically on page 73.

10) Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. Each of claims 3 and 4 can be infringed by an antibody fragment which does not infringe the antibody of claim 1, from which they depend. See M.P.E.P. 608.01(n)III. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 120 states that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the

same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

11) Claims 1 and 5 to 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of the McVitie et al. (P.N.A.S. 88:1441-1445, Feb. 1991) et al. and David et al. (BBRC 179(2):824-829, 16 Sep. 1991) publications, which provided a written description of the claimed antibodies. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application "if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application". Because the preliminary amendment which was filed on 29 January of 2002 could not be entered, the instant specification only contains a reference to two previous applications which had been abandoned prior to the filing of the instant application. Upon perfection of Applicant's claim to priority based upon the additional applications listed in the unentered preliminary amendment, the instant rejection will be withdrawn.

12) Claims 1, 2 and 5 to 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Fraser et al. publication (J. Cellu. Biochem. 21:219-231, 1983). The instant specification discloses that the amino acid sequences recited in the instant claims correspond to naturally occurring human and rat D2 dopamine receptors that are indigenous to brain tissue. The instant claims encompass the antibodies that were described on page 230 of the Fraser et al.

publication more than one year before the filing of the instant application because those antibodies were able to "immunoprecipitate the D_2 receptor from a number of sources including human brain". The amino acid sequence recited in the claims would have been inherent to the human D_2 receptor precipitated by the monoclonal antibodies of Fraser et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13) Claims 2 to 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of the McVitie et al. et al. and David et al. publications cited above. Claim 2 differs from claim 1 in requiring the antibody recited therein to be a monoclonal antibody. Claims 3 and 4 are further distinguished from claim 1 because they are limited to binding fragments of an antibody. To produce a monoclonal antibody to the antigenic peptides described in each of McVitie et al. et al. and David et al. publications to achieve a more consistent reagent for the detection of the antigen thereto in a sample would have been *prima facie* obvious to one of ordinary skill in the art in view of the old and well known practice of generating such antibodies prior to the time of the instant invention. To have proteolytically fragmented such antibodies to produce monovalent labeling reagents having antibody specificity would have also been *prima facie* obvious to one of ordinary skill in the art in view of the old and well known practice of generating such fragments. No

secondary references are being cited in support of these rejections simply because the instant specification is completely silent on these additional embodiments. Therefore, Applicant has essentially conceded that the production of such embodiments was a routine practice in the art at the time of the instant invention once a practitioner was provided with a particular antigen. If this is not the case then the instant claims will have to be rejected under 35 U.S.C. 112, first paragraph, because the instant specification provides absolutely no guidance on how to produce the claimed monoclonal antibodies or antibody fragments and appears to be relying on those practices that were well known in the art at the time that the application was filed to provide these missing elements.

14) Claims 3, 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. publication cited above. Claims 3 and 4 differ from the antibody of Fraser et al. because they are limited to binding fragments of an antibody. As indicated in the preceding paragraph, to have proteolytically fragmented the antibodies of Fraser et al. to produce monovalent labeling reagents having the specificity of those antibodies would have also been *prima facie* obvious to one of ordinary skill in the art in view of the old and well known practice of generating such fragments. Further, claim 9 differs from the antibodies of Fraser et al. because it requires the presence of a label. The attachment of a detectable label to an antibody or binding fragment thereof to facilitate the detection and/or quantitation of its respective antigen in a sample was a practice that was old and well known in the art at the time of the instant invention and an artisan of ordinary skill in the art of molecular biology would have found it *prima facie* obvious to

have labeled an antibody of Fraser et al. to facilitate the detection of its respective antigen in a sample at that time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.